# DIVISION OF ENVIRONMENT
# QUALITY MANAGEMENT PLAN

## PART II:

## BUREAU OF AIR AND RADIATION
## QUALITY ASSURANCE MANAGEMENT PLAN

Kansas Department of Health and Environment
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# Section 1

# INTRODUCTION

## 1.1 Purpose of Document

This quality assurance management plan (QAMP) describes the quality management system utilized by the Bureau of Air and Radiation (BAR), Division of Environment, Kansas Department of Health and Environment (KDHE). Quality assurance goals, policies, procedures, organizational responsibilities, evaluation and reporting requirements, and other attributes of the BAR quality management system are addressed within this QAMP. A glossary of technical terms used in this document can be found in Appendix A of the Division of Environment Quality Management Plan, Part I.

## 1.2 Historical Background

The Kansas air quality program was initially authorized for implementation by the Kansas Department of Health and Environment (KDHE; formerly the Kansas Department of Health) with the enactment of K.S.A. 65-3001 *et seq*. by the 1967 Kansas Legislature. The major provisions of these enabling statutes were adopted to simultaneously comply with the requirements of the federal Clean Air Act (42 U.S.C. 1857), which has been amended in 1967, 1970, 1977 and 1990. This federal law establishes the requirements for states to implement approved air pollution control programs within their respective jurisdictions. The initial series of air pollution control regulations implementing the Kansas Air Quality Act were promulgated in 1970 and codified in Article 19 of KDHE's administrative regulations (K.A.R. 28-19-1 *et seq*.). These original regulations have been amended and expanded since that time in order to comply with relevant modifications to the federal requirements and to respond to changing needs within the state. The Bureau of Air and Radiation has been assigned the responsibility for implementation of the air quality program.

K.S.A. 65-5301 *et seq*. establishes a statewide program to license contractors and certify employees performing asbestos abatement work. Operating under this authority, the Air and Asbestos Compliance Section controls work practices and conducts on-site inspections. As a part of its inspection procedures, this portion of the Air Quality program conducts sampling of materials for the identification and quantification of asbestos content.

The Radiation Control Section, operating under K.S.A. 48-1601 *et seq*. licenses and regulates the possession and use of all radioactive materials in the state and maintains a statewide radiation protection program. This section conducts radiological environmental monitoring programs under K.S.A. 48-1601 *et seq*. and K.S.A. 65-3022 *et seq*., which includes monitoring of the environment surrounding the Wolf Creek Power Generating Station.

The Ambient Air Quality Monitoring Program has maintained an approved Quality Assurance Plan and associated standard operating procedures in accordance with 40 CFR 58 since March 23, 1982. Other programs have maintained standard operating procedures in varied formats.

During the 1980s, several Division of Environment monitoring programs developed quality assurance plans independently of the divisional QMP. Other Division of Environment programs were implemented after the initial quality management initiative, and quality assurance plans for these programs were likewise formulated outside the framework of the original QMP. In 1995, these considerations led to a comprehensive revision of the QMP. The revised QMP was presented in three parts. Part I addressed quality assurance management policies and procedures required of all environmental monitoring programs and projects administered by (or on behalf of) Division of Environment. Part II described additional policies and procedures administered by the individual bureaus and offices within Division of Environment. Part III presented quality assurance plans and standard operating procedures for specific environmental monitoring programs/projects administered by the individual bureaus and offices. The revised QMP was approved by EPA on May 23, 1996, and another, minor revision of the QMP was approved by EPA on May 16, 1997. Federal review/approval in both instances was limited to Part I of the QMP.

The current version of the divisional QMP has retained the three-part composition originally adopted in 1995. However, Part I incorporates several new sections and other changes based on the federal guidance document, *EPA Requirements for Quality Management Plans* (EPA QA/R-2). Part II also has been updated to reflect recent organizational changes and the implementation of new duties within the division's individual bureaus and offices. Finally, Part III has been revised to account for changes in environmental monitoring programs and projects administered by these bureaus and offices.

## 1.3 Bureau of Air and Radiation Quality Assurance Goal

The foremost goal of the BAR quality management system is to ensure that all environmental monitoring operations administered by the bureau produce data of known and acceptable quality and support, in a scientifically defensible manner, the informational needs and regulatory functions of BAR of Division of Environment of KDHE.

# Section 2

# QUALITY ASSURANCE POLICIES

## 2.1 Basic Principles

Historically, the terms quality assurance (QA) and quality control (QC) were applied to manufacturing and corporate settings, where they referred to efforts to ensure the integrity of finished goods and services. These terms have gradually gained acceptance within environmental monitoring and research programs, wherein scientific databases and final program reports typically represent the major finished products.

The terms QA and QC are related but not synonymous. Quality assurance encompasses all measures taken by upper management to ensure that the quality of a finished product meets the standards of the company or organization. This includes measures to independently verify the claims of project managers and their staff. As applied to environmental monitoring programs, QA refers to the collective efforts of administrative staff to ensure that field and laboratory data meet the objectives of the organization and are acquired and utilized in an efficient and scientifically defensible manner. Major QA functions include review and approval of program planning documents, auditing of sample collection, sample analysis, and data handling procedures, and evaluating the effectiveness of implemented QC procedures.

Quality control encompasses all of the direct actions taken to achieve and maintain a desired level of quality for a given product. From an environmental monitoring perspective, QC includes all of the measures taken by project managers and field, laboratory and data management personnel to achieve a predetermined level of data reliability. Quality control is applied from the planning and design stages of the monitoring effort, through the implementation stages, to the handling, storage and reporting of accumulated data.

## 2.2 General BAR Policies

The bureau relies on environmental monitoring data to support a multitude of scientific, regulatory and administrative decisions. Accordingly, efforts to ensure, document and improve the quality of these data rank among the most important functions of staff. All monitoring activities performed within the bureau (intramural activities) or conducted on behalf of BAR by independent contractors or consultants (extramural activities) are expected to comply fully with the following general policies:

(1) The objectives of each environmental monitoring program or project shall be clearly delineated during the planning stages of the program/project. These objectives shall be consistent with the mission, policies and priorities of the bureau.

(2) Tolerable levels of data uncertainty shall be identified during the planning stages of each monitoring program/project so that appropriate procedures and resources may be incorporated into the design of the program/project.

(3) Quality assurance and QC measures shall be integrated into all environmental monitoring programs/projects in the most cost-effective manner possible without hindering the attainment of the stated QA objectives.

(4) A quality assurance project (program) plan (QAPP), describing how the activity will achieve the stated objectives and the required level of data reliability, shall be developed by the manager of each environmental monitoring program/project (see the glossary in Appendix A of the Division of Environment Quality Management Plan, Part I). This document shall be reviewed and approved, at a minimum, by the supervising section chief or district environmental administrator (DEA) and by the bureau/office QA representative prior to initiation of data collection (section 4.1.1).

(5) Sample collection, sample analysis, and data management activities shall be subjected to periodic evaluation by supervisory personnel and outside auditors to identify and correct deficiencies and enhance the credibility of each monitoring program/project.

(6) Measures shall be instituted within each environmental monitoring program/project to ensure that the quality of obtained environmental data is accurately and permanently documented.

## 2.3 Programs and Activities Subject to Policies

The bureau engages in an array of environmental monitoring operations (section 3.1). Data are routinely collected on the concentrations of physicochemical and radiological contaminants in the air. Additional information is obtained on contaminant levels in industrial air emissions. At some ambient monitoring stations, supporting data are gathered on meteorological conditions. Information obtained through these efforts is used to identify and prioritize environmental problems, establish appropriate limits on the kinds and amounts of pollutants released into the environment, and monitor the effectiveness of pollution abatement and cleanup actions. Collectively, these monitoring efforts play a crucial role in protecting public health and the natural resources of Kansas.

The requirements of the BAR QAMP are applicable to all environmental monitoring and measurement operations performed, funded or required by the bureau. This includes virtually all intramural and extramural environmental monitoring programs/projects. However, it is recognized that unusual or unprecedented situations may require immediate responses based on the best professional judgement of staff rather than the provisions of preexisting and approved QAPPs. To the extent practicable, such emergency responses should be based on established procedures.

Outside entities engaged in environmental monitoring operations under contractual agreement with

the bureau must develop QAPPs and SOPs consistent with sections 4.1.1 and 4.1.2 of this document. Alternatively, they must abide by QAPPs and SOPs developed by bureau staff for the specific type of program/project of interest. All such QAPPs and SOPs, whether developed within or outside the bureau, must be reviewed and approved by the appropriate program/project manager, supervising section chief/DEA, and bureau/office QA representative. Environmental monitoring contracts awarded by BAR must contain provisions that ensure formal QAPPs are prepared and approved prior to the initiation of data collection. All QAPPs and SOPs associated with contractual monitoring operations must be maintained in an updated condition. Proposed changes in the work performed under a monitoring contract and associated QAPP must be reviewed and approved by the appropriate program/project manager, supervising section chief/DEA, and bureau/office QA representative prior to implementation.

Some regulated entities are required by the bureau to monitor their contaminant releases into the environment. On occasion, these entities are required to perform more comprehensive pollutant transport, fate, and environmental impact studies. Bureaus/offices requiring regulated entities to perform some level of environmental monitoring generally are expected to develop standardized QAPPs and SOPs compatible in coverage and form with the bureau QA documentation. Alternatively, bureaus/offices may direct regulated entities to develop QAPPs and SOPs and submit them to BAR for review and approval. All such documents, whether developed externally or by bureau staff, must be approved by the appropriate program/project manager, supervising section chief/DEA and bureau/office QA representative prior to implementation.

# Section 3

# QUALITY ASSURANCE ORGANIZATION

## 3.1 Structure of the Bureau of Air and Radiation

The regulatory, planning, and data gathering and analysis functions of BAR are described for each section below. A more detailed description of the environmental monitoring activities can be found in the BAR Quality Assurance Program Plans (QAPP).

The Air Permit Section (APS) is responsible for the review and issuance of construction and operating permits for pollution emitting facilities. The APS is not involved with environmental monitoring activities.

The Air and Asbestos Compliance Section (AACS) evaluates compliance with air quality regulations, issues licenses and certifications to firms and individuals engaged in asbestos abatement activities, and administers the Kansas chemical information reporting program. The AACS will have a QAPP for asbestos monitoring and a QAPP for in-stack emission monitoring.

The Air Monitoring Services Section (AMSS) maintains an emission inventory of regulated facilities and maintains the statewide ambient air quality monitoring network. The AMSS will have one QAPP for the ambient air quality monitoring network which monitors criteria pollutants (those pollutants for which an ambient air quality standard exists). The AMSS will have another QAPP for the ambient air quality monitoring network which measures non-criteria parameters (including meteorological parameters).

The Air Planning and Assessment Section (APAS) evaluates the state's overall air quality status, formulates air pollution mitigative strategies, and develops air quality regulations and implementation plans. The APAS is not involved with environmental monitoring activities.

The Radiation Control Section (RCS) licenses, registers and inspects radioactive materials and radiation producing equipment used in medicine, research and industry and also monitors the environment surrounding the state's only nuclear power plant. The RCS will have a QAPP for environmental monitoring.

An organizational chart illustrating the bureau's current administrative and QA hierarchy is shown in Appendix A. More detailed organizational charts for each environmental program can be found in the QAPPs.

## 3.2 Administrative Responsibilities

The phrase "administrative staff" in the following discussion refers to supervisory employees directly or indirectly responsible for one or more of the bureau's environmental monitoring

programs/projects and generally exercising some authority over at least one lower tier of supervisory staff. Included among the administrative staff are the bureau director, bureau QA representative, and section chiefs. Each of these employees plays a designated role in the bureau quality management system, as described below:

Bureau Director - This supervisory person oversees the development, revision and implementation of the bureau/office QA management plans (Part II of QMP). With the assistance of the bureau/office QA representative and section chiefs, he/she ensures that the requirements of these management plans are fulfilled in the most cost effective manner possible without hindering attainment of the stated QA objectives. The bureau director prioritizes the training and continuing educational needs of staff and develops funding proposals to accommodate these needs, as necessary.

Bureau QA representative - This employee is directly responsible for reviewing and approving QAPPs and SOPs administered by the bureau. He/she also provides guidance to program/project managers involved in the preparation and implementation of these documents. Within the bureau, the bureau QA representative operates under a degree of autonomy which allows him/her to make independent assessments of QA performance and the need for corrective action. The bureau QA representatives analyzes QA evaluation reports and related information submitted by section chiefs and program/project managers. The bureau QA representative works with these supervisory staff and the divisional QA officer in the resolution of identified QA problems and concerns.

Section chiefs - These employees generally are responsible for more than one environmental monitoring program/project and may supervise other, front line supervisors such as program/project managers. They oversee the QA aspects of environmental monitoring programs/projects on an ongoing basis, identify QC deficiencies within their respective programs/projects, track the QC performance of staff, and participate in the periodic review and revision of the bureau QA management plans (Part II of QMP) and associated QAPPs and SOPs (Part III of QMP). Section chiefs coordinate closely with program/project managers to ensure that all applicable QA and QC requirements are routinely and correctly implemented.

## 3.3 Role of Program/Project Managers

Managers of environmental monitoring programs/projects work closely with their staff to ensure that all QAPP and SOP requirements are implemented in a timely, consistent and technically appropriate fashion. Together with the section chiefs, these managers strive to improve the efficiency of environmental monitoring operations through the prudent, day-to-day allocation of staff and other resources. They also bring the QC training needs of staff to the attention of their section chiefs, develop QAPPs and SOPs for new monitoring initiatives, and periodically review and revise existing QAPPs and SOPs to meet the evolving informational needs of the bureau.

## 3.4 Staff Responsibilities

BAR staff involved in the collection and analysis of environmental monitoring data play an important role in the implementation of the BAR QAMP. To a large extent, the quality and usefulness of the environmental data collected by the bureau reflect the willingness of these staff to abide by approved QAPPs and SOPs and to participate constructively in the ongoing review and revision of these documents. Because they carry out the provisions of these plans and procedures on a routine basis, these staff often develop a keen understanding of the technical strengths and weaknesses of the bureau's environmental monitoring operations. Program/project managers and other supervisors are expected to solicit input from these staff when developing new or revised QAPPs and SOPs.

# Section 4

# QUALITY SYSTEM DESCRIPTION

The BAR quality management system for environmental monitoring operations centers around parts I, II and III of the QMP and the following related actions: management system reviews, program/project audits, data quality assessments, internal program/project reviews, staff/supervisor performance evaluations, and annual program/project evaluations. The following discussion considers the major elements of the QMP and each of these referenced actions, in turn.

## 4.1 Quality Management Plan

Part I of the QMP establishes the overarching framework for the divisional quality management system. It is subject to ongoing review and revision according to the schedule established in section 11, below. Although primary responsibility for updating Part I of the QMP rests with the divisional QA officer, input from bureau/office QA representatives and other administrative staff is considered an integral aspect of this process. Minor revisions to Part I of the QMP are subject to the review and approval of the divisional QA officer and division director. Major revisions, reflecting significant changes in the divisional quality management system, require the approval of the divisional QA officer, division director, KDHE general counsel, KDHE secretary, EPA regional QA manager, and EPA regional administrator. Changes constituting major revisions are identified by the divisional QA officer in consultation with the division director and EPA regional QA manager.

Part II of the QMP contains the bureau/office QA management plans. These present a more detailed set of QA expectations tailored to the needs of the individual bureaus and offices but compatible in general form and content with Part I of the QMP. Each bureau/office QA management plan states the mission and developmental history of the bureau/office quality management system and sets forth detailed QA goals, policies, procedures, organizational responsibilities, evaluation and reporting requirements and other technical requirements. Each plan is reviewed at least annually and updated, if needed, by the bureau/office QA representative (section 11). Minor revisions to Part II of the QMP are reviewed and approved by the appropriate bureau/office QA representative and bureau/office director. Major revisions, reflecting significant changes in the bureau/office quality management system, are reviewed and approved by the bureau/office QA representative, bureau/office director, divisional QA officer, and division director. Changes constituting major revisions are identified by the bureau/office QA representative in consultation with the divisional QA officer. Deviations in Part II of the QMP from the overarching divisional policies set forth in Part I of the QMP are approved only under exceptional circumstances and must be clearly explained and justified within the bureau/office QA management plan.

Part III of the QMP contains QAPPs and SOPs utilized by the individual environmental monitoring programs/projects. Owing to their prominent role in the divisional quality management system, QAPPs and SOPs are given special mention in the following paragraphs.

4.1.1 Quality Assurance Program/Project Plans

A QAPP must be developed for each environmental monitoring program/project by the responsible program/project manager and approved by the supervising section chief and appropriate bureau QA representative prior to the initiation of data collection. Quality assurance program/project plans implementing 40 CFR 58, appendix A, must also be reviewed and approved by the divisional QA officer and EPA regional QA manager. Any proposed QAPP which does not meet applicable state or federal requirements must be returned to the program/project manager for further revision, then resubmitted for final approval. If the QAPP originates from a source outside the division and does not meet minimum requirements, it must be returned through the program/project manager to the outside source for revision, then resubmitted to Division of Environment for final approval. For unusual or unprecedented monitoring operations unrelated to 40 CFR 58, appendix A, the bureau/office QA representative may request an additional tier of review/approval by the divisional QA officer. At the discretion of the divisional QA officer, and with the concurrence of the division director, such QAPPs may be submitted to the EPA regional QA manager for federal review and approval.

Each QAPP must be prepared using a standardized document control format in which the report identity, revision number, date of revision, section number, and page number appear in the upper right-hand corner of each page. Each QAPP must contain the following informational elements unless the reviewing bureau/office QA representative determines that a given element falls outside the technical scope of the program/project:

(1) title page identifying program/project, bureau/office, division and agency;

(2) approval page with blocks for appropriate signatures and dates;

(3) table of contents, including a list of any appendices;

(4) overview of program/project, including statement of purpose, developmental history, and any relevant statutory and regulatory requirements;

(5) description (or chart) of organizational hierarchy with accompanying list of participating staff positions and statement of staff responsibilities;

(6) description of data performance criteria expressed in terms of data precision, accuracy, completeness, comparability and representativeness for each parameter of interest;

(7) description of, and rationale for, intended sampling frequency, sampling network design and monitoring site selection criteria;

(8) description of sampling equipment and associated decontamination procedures (reference SOPs, as appropriate);

(9) description of field procedures, including sample collection, analysis, preservation, transport and chain-of-custody procedures and accompanying safety protocols (reference SOPs, as appropriate);

(10) list of laboratory parameters and sample holding times and accompanying description of laboratory analytical and safety protocols (note: SOPs adopted by the Kansas Division of Laboratories or other cooperating laboratories may be adopted by reference, provided they contain the informational elements stipulated in section 4.1.2, below);

(11) description of data validation, storage, transfer, reporting and backup requirements and any special documentation requirements (reference SOPs, as appropriate);

(12) description of equipment testing, calibration and preventative maintenance procedures (reference SOPs, as appropriate);

(13) description of inspection procedures and acceptance requirements for purchased equipment and supplies (reference SOPs, as appropriate);

(14) description of procedures (including statistical procedures) used to evaluate data precision, accuracy, completeness, representativeness and comparability, including a detailed characterization of internal QC procedures and external performance audit requirements;

(15) description of procedures used to evaluate and enhance utility of environmental monitoring data including, but not necessarily limited to, procedures and assumptions applied in the identification and treatment of (a) outliers and other anomalous data, (b) nonlinear data requiring statistical transformation, and (c) values reported as "less than" or "greater than" established reporting limits;

(16) description of corrective action procedures for out-of-control situations;

(17) description of procedures for determining the quality of ancillary data acquired from external sources not subject to the provisions of the divisional QMP (e.g., meteorological, hydrological, geological, chemical and/or biological data obtained from other state and federal agencies); and

(18) description of program/project deliverables (electronic databases, summary statistics, illustrative materials, interim and final reports, etc.) and schedule for completion.

Additional points to consider when preparing a QAPP are presented in the EPA documents *Guidance for Quality Assurance Project Plans* (EPA QA/G-5) and *EPA Requirements for Quality Assurance Project Plans* (EPA QA/R-5).

4.1.2 Standard Operating Procedures

Standard operating procedures document protocols used in the collection, preservation, transport, transfer and analysis of environmental samples and in the collection, validation, storage, retrieval, transfer, backup and analysis of environmental data. As such, they facilitate consistency among staff, serve as valuable references and training tools, and provide formal written records of the methods used to implement environmental monitoring operations. All SOPs must be scientifically rigorous and compatible with the data performance criteria set forth in their respective QAPPs.

Standard operating procedures are developed by the responsible program/project manager and reviewed and approved by the supervising section chief/DEA and bureau/office QA representative. Proposed SOPs which do not meet with the approval of the section chief/DEA or bureau/office QA representative are returned to the program/project manager for further revision, then resubmitted for final approval. If an SOP originates from a contractual source and does not meet with the approval of the program/project manager, section chief/DEA or bureau/office QA representative, it must be returned to the originating source for revision and resubmitted to Division of Environment for final approval.

Approved SOPs may be appended to the end of a QAPP or adopted by reference within the text of a QAPP. All SOPs originating within Division of Environment must employ a standardized document control format in which the report identity, section number, revision number, date of revision, and page number appear in the upper right-hand corner of each page. Elements to consider when preparing an administrative, field, or laboratory SOP are presented in the EPA document *Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality-Related Documents* (EPA QA/G-6). In general, each technical SOP involving field work and related sample and data collection activities will contain the following informational elements, unless the reviewing bureau/office QA representative determines that a given element or combination of elements falls outside the technical scope of the environmental monitoring program/project:

(1) title page with appropriate blocks for approval signatures/dates;

(2) table of contents including a list of any appendices;

(3) introductory statement describing intended application of SOP and providing overview of procedure;

(4) statement of minimal technical qualifications for participating staff;

(5) instructions for calibrating field instruments and performing associated troubleshooting procedures;

(6) instructions for collecting, preserving and handling environmental samples and/or performing environmental measurements, emphasizing health and safety considerations and highlighting any steps requiring special attention, patience or care;

(7) instructions for collecting and analyzing duplicate or replicate samples and for preparing field blanks, spikes and split samples, emphasizing health and safety

considerations and highlighting any steps requiring special attention, patience or care;

(8) instructions for preparing and analyzing samples in the field and performing related troubleshooting procedures, emphasizing health and safety considerations, steps requiring special attention, patience or care, and possible interferences jeopardizing data quality;

(9) instructions for transporting, transferring and storing environmental samples and accompanying field data and records (e.g., notes, logs, photographs, audio tapes, audiovisual tapes), emphasizing chain-of-custody procedures, health and safety considerations, and steps requiring special attention, patience or care;

(10) description of data acquisition, storage, retrieval, transfer, verification, backup and analysis procedures, long-term data/records management procedures, and enabling computer hardware and software;

(11) glossary of technical terms and acronyms employed in SOP (often included as appendix); and

(12) checklist of applicable field equipment and supplies (often included as appendix).

## 4.2 Management System Reviews

A management system review (MSR) is a formal assessment of an organization's quality management system, examining whether the QA policies and procedures being implemented by the organization are consistent with the stated requirements of the organization. As part of the Division of Environment quality management system, MSRs may be conducted for each bureau/office by the divisional QA officer. Auditors from EPA may perform MSRs for the entire division at the discretion of the EPA regional QA manager. The scheduling of these federal and internal MSRs is determined with input from the bureau/office QA representatives, the bureau/office directors, and the division director. Management system reviews conducted by the divisional QA officer and by EPA normally follow the guidelines set forth in the EPA document *Guidance for Preparing, Conducting and Reporting the Results of Management System Reviews* (EPA QA/G-3, draft 1993). Internal and external MSRs help to identify needed corrective actions and opportunities for improving QA performance. The results of these assessments are summarized in writing and distributed to the bureau/office QA representatives, bureau/office directors, and the division director.

## 4.3 Program/Project Audits

Individual monitoring programs/projects may be audited by the divisional QA officer, bureau/office QA representative, federal oversight agency, or an independent third party contracted by the division or oversight agency. Most internal audits are performed by the bureau/office QA representatives based on perceived need. From time to time, the divisional QA officer may plan, perform or oversee

an auditing operation provided (a) the operation has been approved by the division director and (b) the bureau/office QA representative and bureau/office director have been informed of the operation. Internal audits may consider the adequacy of physical facilities, equipment, personnel, training, field and laboratory procedures, record keeping, data validation and management, and other aspects of the targeted monitoring programs/projects. The EPA document *Guidance on Technical Audits and Related Assessments for Environmental Data Operations* (EPA QA/G-7) serves as the principal written guidance for planning and conducting internal audits. Audit findings are shared with section chiefs/DEAs, program/project managers and other participating staff. Corrective actions stemming from audits, and approved and implemented pursuant to section 10.2, below, are addressed by the section chiefs/DEAs in annual program/project evaluation reports (section 4.7).

## 4.4 Data Quality Assessments

Data quality assessments are statistical evaluations which determine whether the type, quantity and quality of environmental data collected by a monitoring program/project support the informational needs of the administering bureau/office and the division. These assessments focus largely on sampling design and monitoring frequency and the general adequacy of the collected data relative to the stated purpose of the monitoring effort. The EPA document *Guidance for Data Quality Assessment: Practical Methods for Data Analysis* (EPA QA/G-9) serves as the principle written guidance for divisional data quality assessments. Such assessments are performed by the bureau/office QA representatives or section chiefs/DEAs based on perceived need. The results of data quality assessments are conveyed to all program/project participants. Corrective actions stemming from these assessments are addressed by section chiefs/DEAs in the end-of-year program/project evaluation reports (section 4.7).

## 4.5 Internal Program/Project Reviews

Quality control aspects of routine environmental monitoring operations are subject to ongoing review by the responsible program/project managers and section chiefs/DEAs. Program/project managers are expected to cooperate fully with administrative requests for information on data precision and accuracy and overall QC performance. Section chiefs/DEAs are expected to track the QC and supervisory performance of program/project managers, assist these managers in identifying QC deficiencies within their respective programs/projects, and facilitate necessary corrective actions. Results of internal reviews conducted by section chiefs/DEAs are summarized in the annual program/project evaluation reports (section 4.7).

## 4.6 Staff/Supervisor Performance Evaluations

Position descriptions and performance evaluations shall reflect the QA and QC functions and performances of staff. All staff involved in environmental monitoring operations are expected to carry out their responsibilities under the BAR QAMP to the best of their abilities. Administrative staff and program/project managers are expected to foster an appreciation for the role of QA and QC among their staff. In turn, program/project managers and administrative staff shall carefully

consider the QA and QC opinions and insights of their staff. The quality and credibility of the bureau's environmental monitoring efforts ultimately depend on the willingness of all employees to work as a team, learn from their mistakes, and continually strive for improvement.

## 4.7 Annual Program/Project Evaluations

End-of-year program/project evaluations shall be conducted by section chiefs/DEAs and the results submitted, in writing, through the appropriate bureau/office QA representative to the bureau/office director and divisional QA officer by February 15 of the following year. These written evaluations shall indicate when, how, and by whom the evaluation was conducted and describe the specific aspects of the programs/projects subjected to review. They shall include a summary of important findings and recommendations for any necessary corrective actions. Section chiefs/DEAs shall discuss the findings of these evaluations with program/project managers and participating field, laboratory, and data management staff.

## 4.8 Annual Divisional Quality Assurance Report

By March 15 of each year, the divisional QA officer shall prepare a written report which summarizes the QA performance of the division during the preceding calendar year and presents recommendations for improving the divisional quality management system. This report shall be submitted to the division director for review and approval. Upon approval by the division director, a copy of the report shall be submitted by the divisional QA officer to the EPA regional QA manager for informational purposes only.

# Section 5

# PERSONNEL QUALIFICATIONS AND TRAINING

## 5.1 Personnel Qualifications

All bureau employees involved in the collection, handling and analysis of environmental samples or in the collection, storage, retrieval, transfer and examination of environmental data must possess the minimum level of education, training and experience necessary to meet the demands of their position (as reflected in the class specifications for the job position or in the employee position description). The knowledge and skills possessed by staff and supervisory personnel strongly influence the quality of environmental monitoring data, the interpretation of these data, and the appropriateness of most administrative and regulatory actions taken by the agency.

## 5.2 Continuing Educational Opportunities

Methods employed in the collection and analysis of environmental samples and environmental data are subject to continual review and improvement. Occasional conceptual or technological breakthroughs may rapidly antiquate existing procedures and protocols and require extensive training or retraining on the part of staff. Continuing educational courses offered by some colleges or vocational educational institutions may fulfill these training needs. Staff participating in such courses may be reimbursed by the bureau provided the course subject matter is within the general scope of the employee position description, funds for training have been set aside within the budget of the beneficiary program/project, requests for reimbursement have been approved prior to attending training, and participation is otherwise allowable under prevailing agency training and travel policies.

## 5.3 Quality Assurance Training

Bureau/office QA representatives are responsible for working with section chiefs/DEAs and program/project managers to ensure that all staff implementing QAPPs and SOPs are familiar with their responsibilities under the BAR QAMP and have received an appropriate level of QA training. As training opportunities and agency resources allow, section chiefs/DEAs and program/project managers are expected to complete the following (or equivalent) EPA training courses: *Orientation to Quality Assurance*, *Systematic Planning Process (Data Quality Objectives)*, *Quality Assurance Project Plans*, and *Standard Operating Procedures*. The divisional QA officer and bureau/office QA representatives are similarly expected to complete the above-mentioned courses and the following (or equivalent) EPA courses: *Quality Management Plans* and *Data Quality Assessments*. As resources and work priorities allow, other employees shall be encouraged to participate in QA training courses offered by EPA. Quality assurance training needs shall be addressed by section chiefs/DEAs in the end-of-year program/project evaluation reports discussed in section 4.7, above.

## 5.4 Supervisory Expectations

The quality of the bureau's environmental monitoring data is strongly influenced by the level of staff training, experience and preparation. Section chiefs/DEAs are expected to address the general training needs of staff within the annual program/project evaluation reports. This information is incorporated annually into the BAR budget prepared by fiscal staff, the bureau director and the section chiefs. To broaden the experience of staff, supervisors may provide occasional opportunities for interested employees to participate in activities outside their daily work routines (i.e., interprogram cross-training opportunities). Such activities must be within the general scope of the employee classification specifications and conform to the training requirements presented in sections 5.5 and 5.7, below.

## 5.5 New Employee Orientation

Supervisors shall ensure that new employees (including newly hired employees and recent transfers or cross trainees from other programs/projects) receive a thorough indoctrination into the QA and QC policies and procedures of the division and the applicable bureau/office and program/project. Part I of QMP and applicable bureau/office QA management plans, QAPPs and SOPs, shall be required reading on the part of new employees. Apart from QA and QC considerations, supervisors shall ensure that new employees participate in orientation and training seminars required by the KDHE Office of Human Resources Management. Similarly, new supervisory employees are expected to successfully complete the introductory training course for supervisors offered by the Department of Administration. Safety procedures shall be thoroughly reviewed before any new employee engages in a potentially hazardous duty. New employees must demonstrate a satisfactory understanding of safety considerations before they are permitted by their supervisors to participate independently in any potentially hazardous activity (section 5.7).

## 5.6 Annual Review Affidavit

All BAR employees participating in environmental monitoring activities shall review Part I of the QMP and applicable portions of parts II and III of the QMP at least once each year. Upon completion of this review, each employee shall sign an affidavit indicating he/she has read the appropriate QA documentation. The signed affidavit shall be routed through the immediate supervisor and bureau/office QA representative to the divisional QA officer. This review requirement shall be incorporated into the employee's written job expectations and factored by the immediate supervisor into the employee's annual performance evaluation.

## 5.7 Safety Considerations

Field and laboratory staff participating in monitoring programs/projects encounter potentially hazardous situations on a frequent basis. In addition to the routine possibility of automobile, boating or equipment accidents, employees may encounter slippery surfaces, toxic substances, fire or electrocution hazards, infectious microorganisms, vicious animals, belligerent persons, or other threatening situations. Injuries or illnesses resulting from such situations may lead to substantial human suffering and, from a QA and QC perspective, deprive monitoring programs/projects of the

services of valuable employees. To minimize this risk, field and laboratory staff must observe all safety requirements set forth in applicable QAPPs and SOPs (sections 4.1.1 and 4.1.2, above) and in the Interim Division of Environment Safety Policy and subsequent divisional safety policies.

# Section 6

# PROCUREMENT OF GOODS AND SERVICES

## 6.1 Procurement of Services

Contractual services involving the acquisition or analysis of environmental data shall be planned and controlled to ensure that these services meet applicable technical and QA requirements. All contracts for services shall require a QAPP to be developed by the outside contractor and submitted to BAR for review and approval prior to the initiation of data collection (section 4.1.1). Procurement of services shall comply with procedures described in the KDHE guidance notebook *Purchase Procedures and Payment Process*. Contracts shall reference or contain specific drawings, regulatory requirements, specifications, codes, standards, standard methods, procedures and/or instructions that describe the services to be provided by the contractor. Contracts also shall specify minimal requirements for evaluating the suitability and acceptability of any data, reports or other deliverables stemming from the contractual agreement. Program/project managers shall be directly responsible for ensuring that deliverables meet the requirements stipulated in the contracts. Section chiefs/DEAs and bureau/office QA representatives are expected to assist program/project managers in resolving any questions relating to the QA and QC aspects of contractual services.

## 6.2 Procurement of Equipment and Supplies

The procurement of equipment and supplies (goods) for environmental monitoring operations shall be planned and controlled to ensure that the quality of obtained goods is documented and meets the technical requirements of BAR. Procurement of goods shall in all instances abide by the procedures described in the KDHE guidance notebook *Purchase Procedures and Payment Process*. Quality assurance specifications shall be clearly indicated in purchase orders or related procurement documents. As needed to comply with data performance criteria, reference shall be made in the procurement documents to specific regulatory requirements, specifications, codes, standards, methods, procedures, or instructions. The procurement documents shall specify minimal technical requirements for acceptance of goods by BAR. Certificates of conformance shall accompany the delivery of chemical reference standards, calibration gases, calibration and reference equipment, and similar goods. Program/project managers (or their designees) shall ensure that all technical specifications are met before goods are accepted by BAR. Section chiefs/DEAs and bureau/office QA representatives shall assist in these activities, as needed. This requirement does not apply to services, equipment and supplies purchased under statewide contracts developed by the Division of Purchases, Department of Administration, on behalf of state agencies.

# Section 7

# COMPUTER TECHNOLOGY

## 7.1 Computer Hardware and Software

All purchases of computer hardware and software must be approved in advance by the KDHE Office of Information Systems (OIS) and abide by the purchasing requirements described in the KDHE guidance notebook *Purchase Procedures and Payment Process*. Anti-virus software approved by OIS shall be installed and utilized on all BAR lap-top and desktop computers, minicomputers and mainframe systems used for storage, retrieval, exchange, backup and/or analysis of environmental data.

## 7.2 Data Entry Requirements

Environmental data (and metadata) manually entered into a state or federal computer database by any BAR employee shall be examined and verified by at least one other BAR employee familiar with the database. This process shall entail the selection of a representative, randomly selected sample of data and the documentation and correction of any data entry errors. The percentage of data subjected to review, the method of review, and the reviewer shall be specified in the approved QAPP. Staff transferring data electronically shall perform random spot checks of the transferred data and report any problems to OIS (or the external cooperating entity) for further investigation and resolution. Persistent or recurring problems also shall be reported to appropriate supervisory staff and the bureau/office QA representative for determination of necessary corrective actions. Such problems shall be addressed in the end-of-year program/project evaluation reports (section 4.7).

## 7.3 Verification of Calculations

Computer-based mathematical, statistical, geographical and graphical programs and models involving environmental data shall be tested before application and periodically thereafter. The reliability of software for performing calculations shall be tested by comparison to other computer programs, through hand calculations involving randomly selected data, or through other appropriate means. The reliability of computer-based calculations shall be verified according to schedules established in applicable QAPPs and whenever a problem is reported within the computational system. Quality assurance program/project plans shall describe the types of computer-based calculations to be performed and prescribe measures for monitoring the precision and accuracy of these calculations. This requirement may be waived in writing by the bureau director for specific applications involving commercial software after review by the bureau director and bureau QA representative. Originals of these waivers shall be retained by the bureau QA representative with a copy forwarded to the divisional QA officer.

# Section 8

# DOCUMENTS AND RECORDS

Changes in the manner of environmental data procurement and in the quality of the data collected by BAR shall be documented for future reference. Original hard copy versions of Part I of the QMP, including the current version and all historical versions, shall be maintained by the divisional QA officer. The bureau QA representative shall maintain original (current and historical) versions of the bureau QA management plans, QAPPs and SOPs administered by BAR.

An electronic representation of the entire QMP (parts I, II and III) shall be maintained on the KDHE internet server in a PDF "read only" format and made accessible to any interested employee or outside party. The divisional QA officer is solely authorized and required to make approved changes to Part I of this electronic representation. Each bureau/office QA representative is similarly authorized and required to update those portions of parts II and III under his/her immediate purview. In general, updates to the electronic representation shall be made within 96 hours of approval of the hard copy revision. Only changes which have been formally approved pursuant to section 4.1 of this document shall be made to the master hard copy and electronic versions of the QMP.

Archiving requirements for environmental monitoring data and routine QC data shall be addressed by the BAR QAPPs. Managers of the various environmental monitoring programs/projects are expected to track QC performance over time and to alert their respective section chiefs and bureau QA representative of any serious deviations from the historical norm or any failure to comply with established data performance criteria.

# Section 9

# PLANNING AND IMPLEMENTATION OF WORK

## 9.1 Planning Requirements

All bureau operations involving the generation and analysis of environmental monitoring data must be systematically planned and documented. The primary planning documents utilized by BAR include the annual bureau budget, work plans associated with other federal grants/agreements, and the QMP. End-of-year program/project reports and the division's annual QA report also serve in a planning capacity by addressing staff training needs, pending corrective actions, and upcoming QA initiatives and assessments (sections 4.7 and 4.8).

The QAPPs contained in Part III of the QMP constitute formal planning tools for both intramural and extramural environmental monitoring programs/projects. In developing a QAPP, the program/project manager is expected to obtain input from the person(s) originally requesting the monitoring data and/or representing the ultimate user(s) of the data. The program/project manager also is expected to solicit comments from field, analytical, data management, supervisory, and other staff likely to participate in the environmental monitoring program/project. Prior to implementation, each QAPP must be reviewed and approved by the supervising section chief/DEA for conformance with organizational work policies and priorities and by the bureau/office QA representative for conformance with applicable QA requirements (section 4.1.1). The EPA document *Data Quality Objectives* (QA/G-4) may be used by the program/project manager as a tool in the QAPP planning and development process.

## 9.2 Implementation Requirements

Environmental monitoring operations shall be implemented by qualified personnel based on approved QAPPs and SOPs. In the event of unforeseen contingencies, any deviation from approved procedures shall be documented and reported by the program/project manager to the supervising section chief/DEA and bureau/office QA representative. The significance of the deviation, and any needed adjustments or corrective actions, shall be determined by the section chief/DEA and bureau/office QA representative with input from the program/project manager and their staff actually performing the work. Staff and supervisory expectations in the event of a departure from approved procedures shall be addressed in the approved QAPP.

# Section 10

# ASSESSMENT AND RESPONSE

## 10.1 Assessments

Assessments are intended to increase the user's understanding of the system being examined and to provide an objective basis for improving the system. Pursuant to section 4, above, environmental monitoring operations covered by this QAMP are subject to internal and external assessments including, but not necessarily limited to, management system reviews, audits, performance evaluations, and data quality assessments. Primary assessment tools selected during the planning stages of a program/project shall be specified within the applicable QAPP and, therefore, subject to review and approval by the supervising section chief, bureau QA representative and, in some instances, the divisional QA officer and EPA regional QA manager (section 4.1.1). The results of routine assessments and any special assessments implemented at the discretion of administrative staff or other parties, and any corrective actions stemming from these assessments, shall be summarized by section chiefs in the end-of-year program/project evaluation reports discussed in section 4.7, above.

The divisional QA officer, bureau/office QA representatives, and other Division of Environment employees called upon to assess the QA and QC performance of an environmental monitoring program/project must have a working familiarity with the technical and management operations performed within that program/project. They also must meet the minimum QA training requirements set forth in sections 5.1 and 5.3, above. These employees are granted the authority to...

(1) access records, data and other forms of documentation needed to evaluate the QA and QC performance of the program/project;

(2) identify and document problems that diminish data quality;

(3) suspend work operations upon detection of a serious adverse condition impacting quality or the safety of staff or the general public;

(4) propose recommendations for resolving documented quality or safety problems; and

(5) independently confirm the effectiveness of any implemented corrective actions.

The results of internal quality assessments must be set forth in writing and forwarded to the program/project manager, section chief, bureau QA representative, bureau director, and divisional QA officer within the time frame stipulated in section 10.2, below.

## 10.2 Corrective Actions

Within ten working days of the completion of an internal QA assessment, the assessor shall document, in writing, the need for any apparent corrective action and share this information with the program/project manager, supervising section chief, bureau QA representative, bureau director, and divisional QA officer. Within thirty working days of receipt of this notification, the program/project manager shall prepare a written response detailing his/her chosen course of corrective action and presenting a schedule for implementing this action. Copies of this response shall be forwarded to the assessor, supervising section chief, bureau QA representative, bureau director, and divisional QA officer. The section chief and bureau QA representative shall be responsible for reviewing, approving, and monitoring the implementation of the chosen corrective action. Corrective actions implemented during the preceding calendar year or scheduled for the upcoming calendar year shall be summarized for each program/project in the end-of-year program/project evaluation reports prepared by the section chiefs (section 4.7).

Copies of program/project QA audit reports prepared by external assessment entities shall be distributed by recipient staff to the appropriate program/project manager, supervising section chief, bureau QA representative, bureau director, and divisional QA officer. Disputes concerning external audit findings and the need for corrective action shall be resolved at the lowest practicable organizational level. Disputes still unresolved after an interval of thirty working days may require intervention by the divisional QA officer and/or division director. Prior to intervention, the divisional QA officer or division director shall notify and consult with the appropriate bureau/office QA representative and bureau/office director. Upon resolution and/or acceptance of external audit findings, the program/project manager shall prepare a written response within thirty working days detailing his/her chosen course of corrective action and providing a schedule for implementing this action. Copies of this response shall be forwarded to the auditor, supervising section chief, bureau QA representative, bureau/office director, and divisional QA officer. The section chief and bureau QA representative shall be responsible for reviewing, approving, and monitoring implementation of the chosen corrective action. Corrective actions implemented during the preceding calendar year or scheduled for the upcoming calendar year shall be summarized for each program/project in the end-of-year program/project evaluation reports prepared by the section chiefs (section 4.7).

Management system review reports submitted by external assessment entities shall be distributed by the divisional QA officer to the bureau/office QA representatives, bureau/office directors, and division director. If a need for corrective action is indicated within an MSR report, a written response shall be prepared by the divisional QA officer within thirty working days and submitted to the division director for review and approval. Bureau/office QA representatives and bureau/office directors shall be provided an opportunity to comment on the proposed response prior to its finalization and forwarding to the external assessment entity. The divisional QA officer shall monitor the implementation of each approved corrective action and summarize the status of each action in the Division of Environment annual QA report (section 4.8).

# Section 11

# QUALITY IMPROVEMENT

Previous sections of this document have discussed specific mechanisms for bringing about the continual improvement of the bureau quality management system. These mechanisms include, but are not necessarily limited to, QA planning requirements (sections 4.1, 4.2, 9.1), internal and external quality assessments (sections 4, 10.1), employee training requirements (section 5), continuing educational opportunities (section 5.2), performance feedback requirements (sections 3.3, 3.4, 4.6), corrective action procedures (sections 10.1, 10.2), end-of-year program/project evaluations (sections 3.2, 4, 5.3, 5.4, 7.2, 10.1, 10.2) and the annual divisional QA report (sections 4.8, 9.1, 10.2). This section addresses two additional mechanisms for ensuring continual improvements in the quality management system: the ongoing review and revision of the QMP itself, and the regular communication of QA and QC concerns and recommendations among BAR staff.

## 11.1 Quality Management Plan Review

To ensure that the bureau quality management system continues to meet the highest scientific and organizational standards, and remains consistent with the primary goal established in section 1.3 of this document, the QMP must be reviewed and updated on a regular basis. At approximately yearly intervals, the divisional QA officer shall review Part I of the QMP, formulate any needed major revisions, and obtain the final approval of the division director, KDHE general counsel, KDHE secretary, EPA regional QA manager, and EPA regional administrator. Similarly, the bureau QA representative shall review the bureau QA management plan (Part II of QMP), formulate any needed major revisions, and obtain the approval of the bureau director, the divisional QA officer, and the division director. Finally, each program/project manager shall review applicable QAPPs and SOPs (Part III of QMP), formulate any needed revisions, and obtain the approval of his/her supervising section chief and bureau QA representative.

As discussed in section 4.1, above, minor revisions to Part I of the QMP normally do not require review and approval beyond the divisional QA officer and division director, and minor revisions to Part II normally do not require review and approval beyond the bureau QA representative and bureau director. Questions regarding the appropriateness of an abbreviated review/approval process for Part I of the QMP are resolved by the divisional QA officer in consultation with the division director and EPA regional QA manager. Similar questions about Part II of the QMP are resolved by the bureau QA representative in consultation with the divisional QA officer. Annual activities related to the review, revision and approval of the QMP normally follow the completion and submission of the program/project evaluation reports in February (section 4.7) and the divisional QA report in March (section 4.8). However, revisions to the QMP or its component parts may be implemented at any time based on urgency of need or staff workload considerations. All approved revisions to the QMP and its component parts are subject to the documentation, tracking, and record keeping requirements of section 8, above.

In addition to the above requirements, Part I of the QMP shall be submitted to EPA for

comprehensive review and approval every five years. The basis for this requirement, and points to consider when submitting Part I of the QMP to EPA, are presented in the document *EPA Requirements for Quality Management Plans* (EPA QA/R-2).

## 11.2 Quality Assurance Communication

The divisional QA officer and bureau/office QA representatives shall meet at least quarterly to review and discuss QA initiatives, training/resource needs, assessments, corrective actions, and other issues relevant to the divisional quality management system. Any critical information exchanged during these meetings shall be communicated to the division director by the divisional QA officer and to bureau/office supervisory personnel by the bureau/office QA representatives. Section chiefs and program/project managers are expected to meet with their staff on a regular basis to obtain feedback on QA and QC issues and to relate this feedback to the bureau QA representative. Additional requirements for regularly communicating QA- and QC-related information may be included in the individual QAPPs (Part III of QMP).

In addition to the regularly scheduled meetings considered above, all environmental monitoring personnel are encouraged to communicate openly and often on QA and QC issues and to express any concerns or recommendations to their immediate supervisors, bureau QA representative, and/or the divisional QA officer. An ongoing exchange of thoughts and opinions on these issues encourages the timely recognition of needed areas of improvement and is a hallmark of a healthy quality management system.

# Appendix A

## Administrative and Quality Assurance Structure of Bureau of Air and Radiation